

CLAIMS:

1. A composition for nasal delivery comprising zolpidem or a pharmaceutically acceptable salt thereof.

5 2. ~~A~~The composition according to claim 1 in the form of a solution or a powder.

3. ~~A~~The composition according to claim 2 in the form of an aqueous solution.

10 4. ~~A~~The composition according to ~~any one of the preceding claims~~claim 1, comprising a salt of zolpidem selected from the hydrochloride, mesilate, citrate, nitrate, lactate, maleate, tartrate, phosphate, succinate, fumarate and gluconate salts.

5. ~~A~~The composition according to claim 4, wherein the salt is the tartrate salt.

15 6. ~~A~~The composition according to ~~any one of the preceding claims~~claim 1, which is in the form of a solution and comprising from 0.8 to 97 mg/ml of zolpidem (expressed as the free base).

7. ~~A~~The composition according to claim 6, comprising from 24 to 80 mg/ml of zolpidem (expressed as the free base).

20 8. ~~A~~The composition according to claim 6, comprising from 2.4 to 16 mg/ml of zolpidem (expressed as the free base).

9. ~~A~~The composition according to ~~any one of the preceding claims~~claim 1, in the form of a solution and comprising a solubility enhancing agent.

10. ~~A~~The composition according to claim 9, wherein the solubility enhancing agent is a cyclodextrin.

25 11. ~~A~~The composition according to claim 10, wherein the cyclodextrin is sulfobutylether- β -cyclodextrin (SBE-CD).

12. ~~A~~The composition according to claim 11, comprising 50 to 700 mg/ml SBE-CD.

30 13. ~~A~~The composition according to ~~any one of the preceding claims~~claim 1, having a pH of from 3.0 to 8.0.

14. ~~A~~The composition according to ~~any one of the preceding claims~~claim 1, additionally comprising chitosan, a salt, a derivative thereof or a salt of a derivative thereof.

15. ~~A~~The composition according to claim 14, comprising from 0.5 to 50 mg/ml of chitosan, a salt, a derivative thereof or a salt of a derivative thereof.

16. ~~A~~The composition according to claim 1, which is an aqueous solution and comprises from 30 to 60 mg/ml of zolpidem tartrate, 100 to 300 mg/ml SBE-CD and 2 to 10 mg/ml of chitosan glutamate.

17. ~~A~~The composition according to claim 1, which is an aqueous solution and comprises from 3 to 20 mg/ml of zolpidem tartrate and 2 to 10 mg/ml of chitosan glutamate.

18. ~~A~~The composition according to ~~any one of claims 1, 2 and 4 to 15,~~claim 1, in the form of a non-aqueous solution.

19. ~~A~~The composition according to claim 18, comprising at least one of ethanol, propylene glycol, polyethylene glycol, glycofurol, benzyl benzoate and a polyoxyethylene castor oil derivative.

20. ~~A~~The composition according to ~~any one of claims 1, 2, 4 and 5~~claim 1, in the form of a powder.

21. ~~A~~The composition according to claim 20, wherein the powder contains granules or microspheres.

22. ~~A~~The composition according to claim ~~20 or 21,~~20, comprising 20 to 70 % by weight of zolpidem (expressed as free base).

23. ~~A~~The composition according to ~~any one of claims 20 to 22,~~claim 20, further comprising a means for improving the rate of dissolution of zolpidem in the nasal cavity.

24. ~~A~~The composition according to claim 23, wherein the means is a cyclodextrin.

25. ~~A~~The composition according to claim 24, wherein the ratio by weight of zolpidem or a pharmaceutically acceptable thereof to cyclodextrin is from 1:0.25 to 1:10.

26. ~~A~~The composition according to claim ~~24 or 25,~~24, wherein the cyclodextrin is sulfobutylether- β -cyclodextrin (SBE-CD).

27. ~~A~~The composition according to ~~any one of claims 20 to 26,~~claim 20, further comprising chitosan, a salt, a derivative thereof or a salt of a derivative thereof.

28. ~~A~~The composition according to claim 27, comprising from 5 to 50 % by weight of chitosan, a salt, a derivative thereof or a salt of a derivative thereof.

5 29. The use of zolpidem or a pharmaceutically acceptable salt thereof in the manufacture of a medicament for nasal administration to a patient in need thereof.

30. ~~Use~~The use according to claim 29 in the manufacture of a medicament for the treatment or prevention of insomnia or for the treatment of a neurological disorder or for the treatment of Parkinson's disease.

10 31. ~~Use~~The use according to claim 30, wherein the neurological disorder is one arising from brain trauma, stroke or spinocerebellar ataxia.

32. A method of administering zolpidem or a pharmaceutically acceptable salt thereof to a patient in need thereof, which method comprise the intranasal administration of a composition as defined in ~~any one of claims 1 to 28,~~claim 1.

15 33. A method of treating or preventing insomnia, which method comprises the intranasal administration of a composition as defined in ~~any one of claims 1 to 28,~~claim 1.

20 34. A method of treating a neurological disorder or Parkinson's disease, which method comprises the intranasal administration of a composition as defined in ~~any one of claims 1 to 28,~~claim 1.

35. A method according to claim 34, wherein the neurological disorder is one arising from brain trauma, stroke or spinocerebellar ataxia.

25 36. A nasal drug delivery device or a dose cartridge for use in a nasal drug delivery device comprising a composition as defined in ~~any one of claims 1 to 28,~~claim 1.